Supreme Court, U.S.
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No. 03-1014

IN THE
Supreme Court of the United States

ELI LILLY & CO.,

Petitioner,

v.

BOARD OF REGENTS OF THE
UNIVERSITY OF WASHINGTON,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITIONER'S REPLY BRIEF

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PARTIES TO THE PROCEEDING-BELOW

Eli Lilly & Company and the Board of Regents of the University of Washington were the parties to the proceedings below.

There are no corporations or publicly held companies that own 10 percent or more of the stock of Eli Lilly & Company and Eli Lilly & Company has no parent corporation.

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I. Introduction

The University of Washington ("UW") based its Opposition to Certiorari on the discretion accorded the PTO in 35 U.S.C. 135(a), not on the merits of the PTO's exercise of that discretion under the facts of this case or on the patentability of the claim the PTO awarded it. But it is the facial invalidity of UW's claim that highlights why the PTO overstepped its discretion here. As Judge Lourie stated in his dissent in the appeal below, the PTO's discretion "is cabined by the requirement that it not be exercised contrary to the statute under which the Director operates the PTO . . . ." App. 19. Indeed, the PTO has wandered from the Patent Statute by issuing two patents for one invention.

II. Argument

A. There Is an Overwhelming Public Interest That the PTO Hold an Interference So That Only One Valid Patent Is Issued for One Invention.

In its brief, UW asserted that there is no public interest in the "particularly unique" facts of this case. *See* UW Opp. at 22. But then UW asserted that, if an interference were held in this case, many other similar interferences would also have to be held, overwhelming the PTO. *See* UW Opp. at 18. UW cannot have it both ways - either Lilly's requested interference is of interest to patent owners or not. In fact, while the facts of this case are not so common as to overburden the PTO, patents are an integral part of the nation's economy, and there *is* overwhelming interest among patent owners and the public in the issuance of valid patents, particularly under the facts of this case.

Evidence of this public concern is found in the *amicus* briefs filed in support of Eli Lilly & Co. ("Lilly") on appeal. Although UW attempted to denigrate the *amici* who filed briefs in support of holding an interference, *see id.* at 12, two innovative companies, Genentech, Inc. and Guilford Pharmaceuticals, Inc., expressed their concern about the PTO's decision to issue two patents for one invention. These companies explained that they need to be confident that their earlier invented species claims will not be undermined by a party who later files a dominating genus claim.

In contrast to these *amicus* briefs, there were no briefs filed by any members of the public in support of UW or the PTO. Despite UW's arguments, it appears that there is no public concern about restricting the PTO's discretion to ensure compliance with the statutory scheme. Similarly, while UW cited two comments in support of the PTO's announcement of the "two-way test" in the Federal Register, *see* UW Opp. at 18-19, it failed to mention that there were seven comments filed opposing the "two-way test," including comments by groups representing many with an interest in a strong patent system, such as the Intellectual Property Owners Association and American Intellectual Property Law Association. *See* Comments on Standard for Declaring an Interference, *available at* http://www.uspto.gov/web/offices/dcom/bpai/rule/ab29.html. That UW concludes from this evidence there is no public concern about the issuance of two patents for one invention reveals an apparent attempt to divert attention from the real issues and facts of this case.

B. UW Has Never Defended Its Genus Claim or Explained How It Is Patentable Under the Patent Statute, But Instead Justifies the Federal Circuit's Decision Based on the PTO's Discretion

Despite the overwhelming public concern that the PTO issue valid patents, UW has never defended the validity of its broad patent claim. For that matter, neither the PTO nor the Federal Circuit ever explained how their decisions uphold the Patent Statute, which requires only one patent to be issued for each invention, and only to the first to invent. *See* 35 U.S.C. § 102(g). Instead of demonstrating the patentability of UW's broad claim, UW, like the PTO, has only invited Lilly to challenge its validity in district court, knowing the disadvantages Lilly would encounter there. *See* UW Opp. at 23 and App. at 64.

In fact, UW cannot defend the patentability of its broad claim, because without an interference the presumption of 37 C.F.R. § 1.657(a) provides that UW invented this genus claim after Lilly invented its species, and therefore is anticipated by Lilly's species. *See In re Slayter*, 276 F.2d 408 (C.C.P.A. 1960); *see also Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 781 (Fed. Cir. 1985).

UW argues that its claim is valid due to the mere fact that it was issued, *see* UW Opp. at 21, n. 12, but because its patent is involved in an interference, the presumption of validity under 35 U.S.C. § 282 does not apply. *See Lamont v. Berguer*, 7 U.S.P.Q.2d 1580, 1582 (Bd. Pat. App. & Int. 1988) ("Accordingly, the presumption of patent validity under 35 USC 282 which must be overcome by a party

charging invalidity is not applicable in interferences."). No other evidence of validity has ever been presented.

UW must be aware of the precarious status of its broad claim, though, and accordingly seems to have chosen to cloak itself in the discretion of the PTO for protection. As long as the PTO imposes a rigid "two-way test" and ignores the evidence of unpatentability before it, UW's genus claim is safe. But, if the PTO were to conduct an interference, UW's broad claim could be rendered invalid conclusively.

To maintain a distraction from these facts, UW has put forth several inaccuracies For instance, UW asserted that the PTO has used its discretion to adopt the "two-way test" to be "ensured that interferences would only be conducted in circumstances where there was no possibility of two patentable inventions." UW Opp. at 7; *see also id.* at 16. Such certainty is impossible under any circumstances, though, because the preliminary motions period in interferences, provided by 37 C.F.R. § 1.633 and § 1.637, allow patentees and applicants to modify the structure of the interference and the involved claims. As a result, it is *never* known when an interference is declared how it will proceed, including whether there is a strategy that the parties can use to salvage patents for themselves.

UW has also sought to distract this Court from the facial invalidity of its broad claim by its characterization of the history of this interference. UW emphasized Lilly's initial error in evaluating the specific genetic sequences claimed by the parties. *See* UW Opp. at 9 and 10, n. 5. Prior to the interference coming before the PTO, though, Lilly acknowledged this error, and has since not disputed that the species claims are separate inventions. Furthermore, in contrast to UW's characterization, *see* UW Opp. at 10, n.5,

Lilly requested an interference with UW's broad claim from the first time it alerted the Examiner to interfering subject matter, not just when it recognized that the species claims do not interfere. That UW presented such an undeservedly disparaging portrait of Lilly only highlights its attempts to avoid defending the merits of the patentability of its claim.

Finally, UW has presented an odd view of the history of the PTO's implementation of the "two-way test." For instance, UW cited the 1984 Notice of Rulemaking in 49 Fed. Reg. 48,416, 48,433 (Dec. 12, 1984), *see* UW Opp. at 6, and *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988), *see* UW Opp. at 7, n.3, as evidence of the origin of a "two-way test." These references address "counts," tools used to compare the interfering claims, but not the interfering claims themselves. Because counts have never been at issue in this case, while the *claims* are, UW should have recognized that these proffered authorities are irrelevant.

Similarly, UW relied on *Chiong v. Roland*, 17 U.S.P.Q.2d 1541, 1544 (Bd. Pat. App. & Int. 1990), and *Hester v. Allgeier*, 687 F.2d 464, 465-67 (C.C.P.A. 1982), *see* UW Opp. at 6, n.7, but these cases are also irrelevant because in both a species claim was found to be separately patentable from a genus claim. UW has never been able to present a case where a "two-way test" was used to determine that a later filed genus claim was patentable in light of an earlier filed species claim.

In sum, UW's arguments only distract from the real issue of this case: Whether the PTO can refuse to determine the first inventor and instead issue a presumptively invalid and potentially dominating genus claim in a competing patent.

C. Despite UW's Use of Discretion as a Shield, the PTO Does Not Have Unlimited Discretion, But Must Abide by the Patent Statute as a Whole

UW denied that the Patent Statute, particularly 35 U.S.C. § 102(g), and the case law conflict with the PTO's exercise of discretion to issue two patents for one invention. *See* UW Opp. at 14 and 15. To conclude this, UW donned blinders and looked only at 35 U.S.C. § 135(a), proclaiming it to be "the only provision in the Patent Statute that addresses interferences." *Id.* at 14. UW cannot truly believe that 35 U.S.C. § 135(a) is the *only* provision of the Statute that applies when one is in interference. Surely, the other provisions of the Statute are not rendered void by an interference.

Indeed, as this Court held in *MCI Telecomm. Corp. v. American Tel. and Tel. Co.*, 512 U.S. 218, 229 (1994), and *United States v. Larionoff,* 431 U.S. 864, 873 (1977), Congress's intent in the statutory scheme as a whole must be adhered to when an agency acts. "When Congress gives an agency its marching orders, the agency must obey all of them, not merely some." *Public Citizen v. Nuclear Regulatory Comm'n,* 901 F.2d 147, 156 (D.C. Cir. 1990). And in fact, the PTO's own rules for interference proceedings specifically enable the parties to raise all patentability questions. *See* 37 C.F.R. § 1.633(a).

35 U.S.C. § 102(g) is not a discretionary provision of the Patent Statute. It must be heeded, regardless of other provisions that give the PTO discretion. Abiding by § 102(g) is not, as UW characterized it, picking and choosing among congressional enactments. It is one of a number of fundamental requirements imposed by the Statute on the

PTO, which the PTO must fulfill before issuing a patent. The statute has never been interpreted to require the PTO to use "extreme" means to find evidence not presented to it, as UW ridiculously suggested. *See* UW Opp. at 20. But at the same time the Statute cannot be interpreted to mean that the PTO can ignore evidence of unpatentability properly presented to it.

CONCLUSION

The public interest lies in having only valid patent claims issued by the PTO. To accomplish this, the PTO must abide by the Patent Statute in its entirety when exercising its discretion. Here, though, how issuance of UW's broad claim without an interference complies with the Statute has never been explained, but merely overlooked in UW's and the Federal Circuit's eagerness to accord the PTO discretion.

Respectfully submitted,

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